ATHLETES FOOT- miconazole nitrate spray Walgreen Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Walgreen Co. Athlete's Foot Powder Spray Drug Facts

Active ingredient

Miconazole nitrate 2%

Purpose

Antifungal

Uses

- proven clinically effective in the treatment of most
- athlete's foot (tinea pedis)
- ringworm (tinea corporis)
- jock itch (tinea cruris)
- effectively relieves
- itching
- cracking
- burning
- scaling
- discomfort

Warnings

For external use only

Flammable: Do not use near flame or spark or while smoking.

Do not use

on children under 2 years of age unless directed by a doctor

When using this product

- avoid contact with the eyes
- contents under pressure. Do not puncture or incinerate or store at temperatures above 120°F (49°C).
- use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

Stop use and ask a doctor if

- irritation occurs
- athlete's foot or ringworm does not improve within 4 weeks

• jock itch does not improve within 2 weeks

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- clean the affected area and dry thoroughly
- shake can well before use
- hold can about 6 inches from the area to be treated
- spray a thin layer over the affected area twice daily (morning and night)
- supervise children in the use of this product
- for athlete's foot, pay special attention to spaces between the toes. Wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.
- use daily for 4 weeks for athlete's foot and ringworm
- use daily for 2 weeks for jock itch
- if condition lasts longer, ask a doctor
- this product is not effective on the scalp or nails
- in case of clogging, clean nozzle with a pin

Inactive ingredients

alcohol SD 40-B, aluminum starch octenylsuccinate, isobutane, isopropyl myristate, propane, propylene carbonate, sorbitan oleate, stearalkonium hectorite, talc

Questions or comments?

1-800-719-9260

Principal Display Panel

MEDICATED - ANTIFUNGAL

Athlete's Foot Powder Spray

Miconazole Nitrate 2%

Cures most athlete's foot

Relieves itching, burning, scaling & cracking

POWDER SPRAY

Compare to Lotrimin® active ingredient

NET WT 4.6 OZ (130 g)



WALGREENS PHARMACIST RECOMMENDED*

MEDICATED • ANTIFUNGAL

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DOT 2P ORG0113-F



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ATHLETES FOOT

miconazole nitrate spray

Product Information

HUMAN OTC DRUG NDC:0363-0557 Product Type Item Code (Source)

TOPICAL Route of Administration **DEA Schedule**

Active Ingredient/Active Moiety

Basis of Strength Ingredient Name Strength MICONAZOLE NITRATE 2 g in 100 g MICO NAZO LE NITRATE (UNII: VW4H1CYW1K) (MICONAZO LE - UNII:7NNO 0 D7S5M)

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19 PJ 0 O 6 2 9 4)	

ISOBUTANE (UNII: BXR49TP611)

ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)	
PROPANE (UNII: T75W9911L6)	
PROPYLENE CARBONATE (UNII: 8 D0 8 K3S51E)	
SORBITAN MONOOLEATE (UNII: 06 XEA2 VD56)	
TALC (UNII: 7SEV7J4R1U)	
STEARALKO NIUM HECTO RITE (UNII: OLX698 AH5P)	

Product Characteristics				
Color	WHITE (to off white)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0363-0557-90	130 g in 1 CAN			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part333C	06/09/2005			

Labeler - Walgreen Company (008965063)

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